

# 2013-2014 Education Plan for VAPHS Human Subjects Investigators and Coordinators

## October 1, 2013-September 30, 2014

### 1. Introduction

In accordance with VAPHS R&D Policy 009, Principal Investigators and Research Coordinators of non-exempt human subjects research studies are required to meet the annual education requirements established by the VAPHS Human Research Protection Program (HRPP) Working Group and endorsed by the VAPHS Research and Development Committee (R&DC). Individuals named as Principal Investigator or Research Coordinator on the VAPHS Research Staff form/ProSPECT submission are subject to the requirements outlined in this plan.

### 2. Requirements

#### A. Education for New Principal Investigators and New Research Coordinators

All new Principal Investigators and new Research Coordinators (i.e., those individuals who have not previously been identified as a Principal Investigator or Research Coordinator on an active non-exempt human subjects project at VAPHS within the past 3 years) must participate in a New Investigator/New Coordinator Quality Assurance Interview. Interviews may be scheduled PRIOR to submission, however, they must be completed no later than 90 days after the date of ACOS/R&D notification that the project may be initiated (in the case of new studies) or no later than 90 days after IRB approval as the PI or coordinator (in the case of active studies being taken over by a new PI or new coordinator)<sup>1</sup>. New Principal Investigators and Coordinators may contact the Research Education Staff to arrange an interview prior to submission or the Research Education Staff will contact the PI and/or Study Coordinator once notification approval has been issued. The interview will focus on issues including, but not limited to:

- Investigator responsibilities
- Working with the VA Central IRB (if applicable)
- Reportable Events
- Recruitment and Screening Procedures
- Informed Consent requirements
- Documentation and record keeping

#### B. Continuing Education:

Principal Investigators and Study Coordinators who have had at least one non-exempt human subjects research study approved prior to October 1, 2013 must fulfill the following continuing education requirements during the education year (October 1, 2013- September 30, 2014), as applicable:

##### 1. Principal Investigators:

Principal Investigators of active, **non-exempt** human subjects research must participate in **at least one** of the following

- a. An annual refresher course provided by the VAPHS Research Education and Policy Office
- b. Demonstrated active participation as a VAPHS IRB, VA Central IRB, or HRPP Committee Member<sup>2</sup>

---

<sup>1</sup> In special circumstances, the VAPHS R&D Committee may grant an exception to the requirement to complete the QA Interview.

<sup>2</sup> Demonstrated participation is verified by proof of attendance at 80% or greater at IRB or HRPP meetings.

- c. Participation in a Post Implementation Quality Assurance Review within the fiscal year. These meetings are at the request of the investigator/study team or one of the VAPHS IRBs and are specifically designed by the Research Education Office to reinforce VA policy and procedure relative to the conduct of a specific study.
  - d. Any other VAPHS Research Education and Policy Office sponsored course or session.
2. Study Coordinators:
- Study Coordinators of active, **non-exempt** human subjects research must participate in **at least two** of the following:
- a. An annual refresher course provided by the VAPHS Research Education and Policy Office
  - b. Demonstrated active participation as a VAPHS IRB or HRPP Committee member.
  - c. Participation in a VAPHS Specific Post Implementation Quality Assurance Review within the fiscal year. These meetings are at the request of the investigator/study team or one of the VAPHS IRBs and are specifically designed by the Research Education and Policy Coordinator to reinforce VA policy and procedure relative to the conduct of a specific study
  - d. Participation in a Society of Clinical Research Associates (SoCRA) or Association of Clinical Research Professionals (ACRP) training.
  - e. Participation in VA Office of Research and Development (ORD) sponsored training, such as HRPP 101, HRPP 201, or a cyberseminar.
  - f. Participation in VA Cooperative Studies Program (CSP) training
  - g. Any other VAPHS Research Education and Policy Office sponsored course.

Individuals interested in obtaining credit for other courses should provide a course description and evidence of participation (if already attended) for evaluation by the VAPHS HRPP Committee.

- 3. Principal Investigators and Research Coordinators who only have active exempt research do not have any continuing education requirements, however they are encouraged to attend/participate in any education session they deem appropriate.
- 4. Co-Investigators and Other Research Staff (which for the purposes of education includes regulatory coordinators, research assistants, consultants, statisticians, and coordinators who are based at another VA facility) are not subject to any education requirement. However, it is **strongly recommended** that any research staff members who will be interacting with research subjects and/or submitting research proposals participate in applicable sessions.

### **3. Education Calendar**

The Research Education Office will provide regular opportunities for individuals to fulfill their requirements. Topics will vary based upon need, however, refresher sessions will be held approximately every 6-8 weeks throughout the year. Additional sessions can be added if necessary.